UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

JESUS TAPIA, an individual, Plaintiff, vs. DAVOL, INC., a corporation; BARD DEVICES INC., a corporation; C.R. BARD, INC., a corporation, and DOES 1-50, Defendants.	CASE NO. 15cv179-GPC(JLB) **ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS** [Dkt. No. 21.]

Before the Court is Defendants Davol, Inc.'s, Bard Devices, Inc. and C.R. Bard, Inc.'s ("Defendants") motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (Dkt. No. 21.) An opposition was filed on October 2, 2015. (Dkt. No. 23.) A reply was filed on October 9, 2015. (Dkt. No. 24.) Based on a review of the first amended complaint, the briefs and the applicable law, the Court GRANTS in part and DENIES in part Defendants' motion to dismiss.

Factual Background

On January 27, 2015, Plaintiff Jesus Tapia ("Plaintiff") filed a complaint against Defendants Davol, Inc., Bard Devices, Inc., and C.R. Bard, Inc. for personal injuries suffered as a proximate result of Defendants' "negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, sale, and/or post-market surveillance and corrective

action of the Bard Composix Kugel Hernia Repair Patch" ("Kugel Patch" or "Patch"). (Dkt. No. 1, Compl. ¶ 1.) On July 28, 2015, the Court granted in part and denied in part Defendant Davol, Inc.'s[1] motion to dismiss with leave to amend. (Dkt. No. 13.) On August 14, 2015, Plaintiff filed a first amended complaint ("FAC"). (Dkt. No. 19.) The allegations in the first amended complaint are almost identical to the facts of the original complaint.

Defendants manufactured and sold the Kugel Patch for use in repairing hernias. (Dkt. No. 19, FAC ¶ 2.) The Kugel Patch at issue was manufactured and sold by Defendants between 2001 and March 2006. (Id. ¶ 22.) The Kugel Patch is a prosthetic device used primarily to repair ventral and inguinal hernias. (Id. ¶ 23.) The Patch is composed of two sides where one side is constructed of a double layer of monofilament polypropylene (mesh), and the other side is a barrier of expanded polytetrafluoroethylene (ePTFE). (Id.) This double layer creates a positioning pocket, in which a polymer "memory recoil ring" is placed. (Id.) During the hernia repair surgery, the Kugel Patch is inserted behind the hernia defect through a small incision. (Id.) The memory recoil ring then allows the Kugel Patch to swing open and maintain its shape during placement. (Id.)

In October 2000, Defendants submitted a section 510(d) notification of intent to market the Kugel Patch with the Federal Drug Administration ("FDA"). (Id. ¶ 24.) The FDA approved the Kugel Patch for marketing as a Class II medical device in January 2001. (Id.) Immediately after the Kugel Patch was placed on the market, Defendants became aware and obtained knowledge it was defective and causing serious injury to those persons in whom it had been implanted. (Id. ¶ 25.)

Defendants were required to conduct post market surveys as part of the device validation process. (Id. ¶ 26.) On or about January 2006, the FDA inspected a Kugel Patch manufacturing facility which resulted in the FDA issuing an Establishment

[1] At the time, Defendants Bard Devices, Inc. and C.R. Bard, Inc. had not yet been served with the complaint. (Dkt. No. 13 at 1 n. 1.) Since then, Defendants Bard Devices, Inc. and C.R. Bard, Inc. waived service. (Dkt. Nos. 14, 15.)

Inspection Report ("2006 EIR"). (Id.) The 2006 EIR found that the post market survey validation process of the device was incomplete and failed to include all data from physicians surveyed during this time, including those which demonstrated unfavorable or "dissatisfied" results. (Id.) According to Plaintiff, these complaints and concerns of physician surveyors were actively concealed by Defendants from Plaintiff, the healthcare community, and other consumers. (Id.)

No later than September 2004, Defendants became aware of serious problems with the weld process involving the memory recoil ring. (Id. ¶ 27.) Despite attempts to correct the problem, the corrective measures were ineffective and the process was still not in control. (Id.) Defendants were aware that these weld issues had existed from the time the Kugel Patch was placed on the market and all current sizes and lots suffered from this defect. (Id.) Plaintiff alleges this information was intentionally withheld from Plaintiff, the healthcare community, the FDA, and other consumers. (Id.)

According to the 2006 EIR, Davol corporate executives informed the FDA that the spring and summer period of 2005 showed a marked increase in the number of adverse event complaints regarding the Kugel Patch and the memory recoil ring. (Id. ¶ 28.) As of August 2005, Defendants received at least the following adverse event reports: seventeen (17) instances of ring breaks, at least one of which resulted in death; two (2) unexplained bowel perforations; four (4) ring breaks during implant procedures; five (5) cases of device deformity; and eight (8) instances of bowel adhesions to the Patch. (Id.)

Despite the increasing number of complaints and complications arising from the Kugel Patch, Defendants failed to cease distribution or notify Plaintiffs, physicians, hospitals, the FDA, or other consumers of the severity of complications associated with the unreasonably dangerous and defective Kugel Patch until late December 2005. (Id. ¶ 29.)

In December 2005, there was a limited recall of "Extra Large" sized Kugel

Patches even though Defendant knew that there were similar serious adverse events as to the nonrecalled Kugel Patch sizes. (Id. ¶ 30.) Defendants also violated federal law by not timely notifying the FDA of the December 2005 recall. (Id.)

The FDA classified the December 2005 recall as a Class 1 recall which is the most serious type of recalls and involve situations where the FDA believes there is a reasonable probability that use of the product will cause serious injury or death. (Id. ¶ 31.)

The recall was due to the breakage of the memory recoil ring that opens the Kugel Patch, under stress or pressure, including the stress of implantation. (Id. ¶ 32.) The Kugel Patch is also known to become deformed and migrate within the body. (Id.) These defects are known to cause severe injuries including, *inter alia*, perforation of the bowel, ring migration through the abdominal wall, abnormal chronic enteric fistulae, infection, abscesses, bowel obstruction, intense abdominal pain, peritonitis, sepsis, and adhesions between the bowel and the Patch. (Id.) The following conditions are symptoms of these injuries: fever, unexplained or persistent abdominal tenderness, vomiting, abnormal bowel movements, tenderness at implant site, abdominal distention, or other unusual symptoms. (Id.)

On March 24, 2006, Defendants expanded the recall to include the following Kugel Patch sizes: 1) "Oval" Patches, 2) "Large Circle" Patches, and 3) "Large Oval" Patches. (Id. ¶ 34.) In January 2007, Defendants expanded the recall for the second time, to include further production lots of the "Large Oval" and "Large Circle" Kugel Patches. (Id. ¶ 35.)

The FDA inspected the Cranston, Rhode Island Kugel Patch manufacturing facility for the second time from January 23, through March 13, 2007. (Id. ¶ 36.) On April 24, 2007, the FDA issued a "Warning Letter" to Defendants that the inspection again uncovered "serious violations of the law" with regards to the quality assurance programs used in manufacturing the Kugel Patch. (Id.)

These violations were of such a degree and nature that the FDA determined the

Kugel Patch to be "adulterated" under section 501(h) of the Federal Food, Drug and Cosmetic Act. (Id.) The warning letter specifically mentions, *inter alia*, the following violations:

a. Failure to establish and maintain adequate corrective and preventative action procedures which ensure identification of actions needed to correct and prevent the recurrence of nonconforming product and other quality problems;

b. Failure to establish adequate management controls to ensure that an effective quality system has been established and maintained;

c. Failure to document the implementation of corrective and preventative actions;

d. Failure to validate your device's design to ensure that the device conforms to defined user needs and intended uses;

e. Failure of your firm to establish procedures to completely address the identification, documentation, evaluation, segregation, disposition and investigation of non-conforming product.

(Id.)

Around December 15, 2005, Plaintiff Jesus Tapia underwent a hernia repair procedure during which a Bard Composix Kugel Hernia Patch (Ref. # 0010202, Lot # 43IPD472) was implanted. (Id. ¶ 37.) On or about January 27, 2013, Plaintiff Jesus Tapia was admitted to the emergency department at Menifee Valley Medical Center. (Id. ¶ 39.) He presented with redness and pain above his Kugel Patch surgical site. (Id.) He was diagnosed with abdominal wall mesh infection and abscess. (Id.) Around February 3, 2013, Plaintiff underwent emergency surgery to remove the Kugel Patch. (Id. ¶ 40.) During the removal procedure, it was noted that the plastic ring that supported the Kugel Patch broke and caused an enterotomy which led to Kugel Patch infection. (Id.)

As a result, Plaintiff will require continuous monitoring of his Kugel Patch related injuries for the remainder of his life. (Id. ¶ 42.) His physical injuries,

proximately caused by his implantation with a Kugel Patch, are severe, life threatening, and permanent, and have adversely impacted the quality of his life. (Id.)

The FAC alleges the following causes of action:

Count I: Product Liability - Negligence;

Count II: Product Liability - Manufacturing Defect;

Count III: Product Liability - Failure to Warn;

Count IV: Product Liability - Breach of Express Warranty; and

Count V: Fraud and Deceit

(Dkt. No. 19, FAC.) Defendants move to dismiss Counts III, IV, and V of the FAC. (Dkt. No. 21.) Plaintiff opposed and Defendants filed a reply. (Dkt. Nos. 23, 24.)

Discussion

A. Legal Standard on Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure ("Rule") 12(b)(6) permits dismissal for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Dismissal under Rule 12(b)(6) is appropriate where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. See Balistreri v. Pacifica Police Dep't., 901 F.2d 696, 699 (9th Cir. 1990). Under Rule 8(a)(2), the plaintiff is required only to set forth a "short and plain statement of the claim showing that the pleader is entitled to relief," and "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A complaint may survive a motion to dismiss only if, taking all well-pleaded factual allegations as true, it contains enough facts to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. "In sum, for

a complaint to survive a motion to dismiss, the non-conclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir. 2009) (quotations omitted). In reviewing a Rule 12(b)(6) motion, the Court accepts as true all facts alleged in the complaint, and draws all reasonable inferences in favor of the plaintiff. al-Kidd v. Ashcroft, 580 F.3d 949, 956 (9th Cir. 2009).

Where a motion to dismiss is granted, "leave to amend should be granted 'unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.'" DeSoto v. Yellow Freight Sys., Inc., 957 F.2d 655, 658 (9th Cir. 1992) (quoting Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986)). In other words, where leave to amend would be futile, the Court may deny leave to amend. See Desoto, 957 F.2d at 658; Schreiber, 806 F.2d at 1401.

B. Count III, Failure to Warn; Count IV, Breach of Express Warranty; Count V, Fraud and Deceit

Defendants argue that the FAC fails to adequately allege causation as to the causes of action for failure to warn, breach of express warranty, and fraud and deceit because Plaintiff only changed the term "the healthcare community" and "physicians" to "his healthcare providers" and "his prescribing physician." They contend that he has not pleaded any additional facts regarding causation. Plaintiff contends that the FAC has sufficiently alleged causation as to all three causes of action.

Under the learned intermediary doctrine, the duty to warn in the case of medical devices runs to the physician, not the patient. Plenger v. Alza Corp., 11 Cal. App. 4th 349, 362 (1992). A manufacturer fulfills its duty to warn if it provides adequate warnings to the physician. Id. at 362 n. 6 (citing cases); see also Brown v. Superior Court, 44 Cal.3d 1049, 1062 n. 9 (1998). In order to prove causation, Plaintiff must allege that an inadequate warning about the medical device risk would have altered the prescribing physician's decision to use the product. Motus v. Pfizer, Inc., 196 F. Supp.

2d 984, 991 (C.D. Cal. 2001); Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004) ("[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician."). The learned intermediary doctrine also applies to breach of warranty claims predicated on a failure to warn claim, see Carlin v. Superior Court, 13 Cal. 4th 1104, 1118 (1996), and fraudulent concealment. See Jones v. Medtronic, 89 F. Supp. 3d 1035, 1048-49 (D. Az. 2015) (granting motion to dismiss fraud claim since there was no allegation the defendant fraudulently induced *her doctor* to use defendants products in *her* surgeries).

The original complaint referenced "physicians" and the "healthcare community" in general. In the Court's prior order granting in part and denying in part Defendant's motion to dismiss, it held that Plaintiff sufficiently alleged what Defendants failed to warn about, the terms of the express warranty, and as to fraudulent concealment, "what" was concealed, "when" it was concealed and "why" it was concealed. However, in granting Defendant's motion to dismiss, the Court concluded that as to the three causes of action, Plaintiff failed to allege that his own prescribing physician was not adequately warned, that his own prescribing physician read and relied on the express warranties contained in the packaging and written advertisements, and that his own prescribing physician would not have used the device had Defendants not concealed material facts. (Dkt. No. 13 at 9-10, 16-17, 20.)

Defendants argue that replacing the words "physicians" and the "healthcare community" in general to "his prescribing physicians" is not sufficient to satisfy the 12(b)(6) standard because Plaintiff fails to provide any additional factual allegations regarding causation such as the circumstances surrounding Plaintiff's physician's decision to use the Patch. Specifically, Defendants assert, "Plaintiff only alleges in conclusory terms that his physician read and relied on express warranties in the packaging and written advertisements, but Plaintiff does allege any facts regarding which specific advertisements his physician read and relied on, whether he read one or

multiple different advertisements, when he read each advertisement, what specific express warranties were contained in each advertisement he read, or what express warranties were contained in the packaging that his physician read and relied on in rendering his treatment decisions." (Dkt. No. 21-1 at 12.)

The Court concludes that Defendants' argument imposes a standard that goes beyond what is required under Iqbal and Twombly. Moreover, Defendants do not provide cases to support their position that a complaint requires pleading specific facts. Instead, the cases cited by Defendants concerning the issue of causation are in the context of a motion for summary judgment, a standard distinct from a motion to dismiss standard. See Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001); Huntman v. Danek Medical, Inc., No. 97-2155-IEG(RBB), 1998 WL 663362, at *5 (S.D. Cal. July 24, 1998); Todd v. Stryker Corp., No. 2:09cv1509-JAM(GGH), 2012 WL 2922727, at *4 (E.D. Cal. May 1, 2012). Second, Defendants cite cases concerning whether the labels are sufficient, In re Clorox Consumer Litigation, 894 F. Supp.2d 1224, 1235 (N.D. Cal. 2012), or whether the particulars of the commercial or advertisement are stated with particularity, Nabors v. Google, Inc., 2011 WL 3861893, at *4 (N.D. Cal. Aug. 30, 2011). However, the Court already ruled that Plaintiff's allegation as to the contents of the failure to warn, and the express warranty were sufficiently pled. Lastly, many cases cited by Defendants concern allegations of no causation, which is distinct from the instant case. See Hawkins v. Medtronic, Inc., No. 13CV499 AWI SKO, 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014) (concerning lack of any causal connection between Plaintiff's injuries and the alleged failure to report adverse events to the FDA as not adequately pled); Knoppel v. St. Jude Medical, Inc., No. SACV 13-383 JVS(ANx), 2013 WL 3803612, at *2-3 (C.D. Cal. May 7, 2013) (failure to provide any allegation that the defect caused Plaintiff's injury); Rhynes v. Stryker Corp., No. 10-5619 SC, 2011 WL 2149095, at *2-3 (N.D. Cal. May 31, 2011) (granting motion to dismiss where there was no allegation that plaintiff was injured by alleged defective product); Currier v. Stryker Corp., No. 11cv1203 JAM-

EFB, 2011 WL 4898501, at *4 (E.D. Cal. Oct. 13, 2011) (case concerning privity for breach of express warranty, not causation); In re Hydroxycut Marketing and Sales Practices Litigation, No. 09MD2087-BTM(AJB), 2010 WL 2839480, at *2 (S.D. Cal. July 20, 2010) (granting motion to dismiss breach of express warranty because there was no allegation that the plaintiff read the language or relied on the language when she bought the product).

Here, the FAC has changed the references of "physicians" and "healthcare community" to "his healthcare providers," (Dkt. No. 19, FAC ¶ 46), and "his prescribing physicians" (id. ¶¶ 73, 85, 96). As to a failure to warn, the FAC alleges that Defendants failed to warn his own prescribing physician and that his own prescribing physician would not have used the Patch if warnings had been given. (Id. ¶ 73.) As to the breach of express warranty, the FAC contends that his prescribing physician read and relied on the express warranties provided in the packaging and written advertisements, and would not have agreed to use the Kugel Patch if his physician had known that the express warranties were not accurate. (Id. ¶ 90.) Lastly, as to fraudulent concealment, Plaintiff complains that his prescribing physician relied on the fraudulent omissions and would not have implanted the Kugel Patch if the true facts had not been intentionally concealed. (Id. ¶ 106.)

These allegations have been deemed sufficient on a motion to dismiss. See Baker v. Bayer Healthcare Pharms., Inc., No. C13-490 THE, 2013 WL 6698653, at *5 (N.D. Cal. Dec. 19, 2013). In Baker, the district court concluded the Plaintiff had sufficiently alleged facts to withstand a motion to dismiss based on the allegation that "Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her or her physician(s). Had the Plaintiff received adequate warnings regarding Mirena, she would not have had the device implanted." Id.

Accordingly, the Court DENIES Defendant's motion to dismiss the causes of action for failure to warn, breach of express warranty and fraudulent concealment.

D. Count V - Fraud/Deceit[2]

Defendants additionally move to dismiss the fraudulent misrepresentation and fraudulent concealment causes of action for failing to satisfy the heightened pleading requirement under Rule 9(b). As to fraudulent concealment, Defendants maintain that Plaintiff has not alleged the role of each Defendant in the concealment. As to fraudulent misrepresentation, Plaintiff has failed to amend the complaint to allege the specific content of the misrepresentations, where they are located, and when and where the misrepresentations were made and by whom." (Dkt. No. 21-1 at 15.) Plaintiff opposes arguing that he has sufficiently alleged a claim for fraudulent concealment but does not address the claim of fraudulent misrepresentation.

In the Court's prior order concerning fraudulent concealment, the "Court has concluded that Plaintiff has sufficiently alleged facts to support the specific facts of what information was concealed. Plaintiff has only failed to assert causation and the role of each Defendant in the concealment." (Dkt. No. 13 at 20-21.) The FAC corrects the deficiency of the original complaint and alleges the role of each Defendant in the alleged concealment. (Dkt. No. 19, FAC ¶¶ 97, 98. 99.) Therefore, the Court DENIES Defendants' motion to dismiss the fraudulent concealment claim.

As to fraudulent misrepresentations, the Court, in the prior order, concluded that Plaintiff failed to allege facts with sufficient particularity under Rule 9(b) concerning the specific content of the misrepresentations, where they are located, and when and where the misrepresentations were made and who made them. (See Dkt. No. 13. at 21.) The FAC does not cure the deficiencies noted by the Court and provides no facts concerning any alleged misrepresentations and only summarily alleges misrepresentations made by Defendants. In addition, Plaintiff does not address this issue in his opposition. With no opposition having been filed on this issue, the Court concludes that Plaintiff concedes the dismissal of the fraudulent misrepresentation

[2]Under fraud/deceit, Plaintiff alleges a cause of action for fraud/deceit which appears to be a claim for "fraudulent concealment" and "fraudulent misrepresentation" as to Defendants Davol, Inc. and C.R. Bard, Inc. (Dkt. No. 19, FAC ¶¶ 93-109.)

claim. Since Plaintiff conceded this issue in the prior motion to dismiss[3] and does not address the deficiency in the FAC in his opposition, the Court GRANTS Defendants' motion to dismiss the cause of action for fraudulent misrepresentation without leave to amend since amendment would be futile at this time. See Schreiber Distrib., 806 F.2d at 1401.

E. Punitive Damages

Defendants contend that the claim for punitive damages fails because Plaintiff has not provided specific facts showing the requisite oppression, fraud or malice. Plaintiff opposes.

California Civil Code section 3294 provides for punitive damages for a violation of state law.

> (a) In an action for the breach of an obligation not arising from contract, where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice, the plaintiff, in addition to the actual damages, may recover damages for the sake of example and by way of punishing the defendant.

Cal. Civ. Code § 3294. While section 3294 is a substantive standard that Plaintiff must meet in order to obtain punitive damages, alleging facts to support a claim of punitive damages is governed by the Federal Rules of Civil Procedure, and does not require particularity. See Kelly Moore Paint Co., Inc. v. Nat'l Union Fire Ins. Co. of Pittsburgh, PA, Case No. 14cv1797-MEJ, 2014 WL 2119996, at *3 (N.D. Cal. May 21, 2014). A complaint does not need to contain detailed factual allegations but it must plead "enough facts to state a claim to relief that is plausible on its face." See Twombly, 550 U.S. at 570.

Here, FAC alleges punitive damages based on "Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare." (Dkt. No. 19, FAC ¶ 111.)

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[3]In the prior motion to dismiss, Plaintiff sought leave to supplement the claim for fraudulent misrepresentation once he had the opportunity to depose his prescribing physician. However, seeking leave to supplement in an opposition is not proper and also premature since the prescribing physician has not yet been deposed.

He further alleges that Defendants intentionally concealed facts regarding the serious risks of harm associated with the use of the product and intentionally downplayed the type, nature and extent of the adverse side effects of the Kugel Patch implant. (Id.) In addition, Defendants had knowledge and were in possession of evidence demonstrating that the Kugel Patch caused serious physical side effects but provided false and misleading information about the product's safety and efficacy. (Id. ¶ 112.) Further, Defendants failed to provide accurate information and warning to the healthcare community that would have dissuaded physicians from surgically implanting the Kugel Patch and consumers from agreeing to being implanted with the Kugel Patch. (Id. ¶ 113.)

These allegations, taken as true, that Defendants knowingly concealed facts regarding the serious risk of harm of using the Patch, and expressly warranted that the Patch was safe and fit for use are sufficient to allege a claim of punitive damages. Thus, at this stage of the proceedings, the Court DENIES Defendants' motion to dismiss the prayer for punitive damages.

Conclusion

Based on the above, the Court GRANTS in part and DENIES in part Defendants' motion to dismiss. Specifically, the Court DENIES Defendants' motion to dismiss the failure to warn (Count III); breach of express warranty (Count IV); and fraudulent concealment (Count V) causes of action. The Court also DENIES Defendants' motion to dismiss claim for punitive damages. The Court also GRANTS Defendants' motion to dismiss the cause of action for fraudulent misrepresentation (Count V) without leave to amend. Defendants are directed to file an answer as provided in the Federal Rule of Civil Procedure.

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The hearing set for November 6, 2015 shall be **vacated.**

IT IS SO ORDERED.

DATED: November 6, 2015

HON. GONZALO P. CURIEL
United States District Judge